

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2247538-1
Certificate Holder: Stryker Instruments,
a division of Stryker Corporation
1941 Stryker Way
Portage MI 49002
USA

Scope: Design and Development, Manufacture, Distribution, and Service Automated Percutaneous Delivery Systems, Bone Biopsy Systems, Bone Cement, Cement Mixing and Application Systems, Bone Cutting and Drilling Devices, Bone Mill Systems, Bone Preparation Systems, Cast Room Systems, Discography Systems, Electronic Surgical Sponge Counters, Fragmentable Dressings, Instruments, Equipment and System Elements for Computer Assisted Surgery, Headworn Lights Battery Powered, Large Bone Powered Surgical Systems, Percutaneous Cement and Systems, Personal Protection Systems, Pneumatic Bone Cutting and Drilling Devices, Pneumatic Tourniquet Systems, Pressure Monitor Systems, Pulsed Irrigation Systems, RF Generator Systems, RF Surgery Instruments, Short Term Bone Fixation Devices, Small Bone Powered Surgical Systems, Soft Tissue Ultrasonic Surgical Systems, Vertebral Augmentation Systems, Waste Management Systems, Wound Closure Devices, Hydrogen Peroxide Ozone Sterilizers, Oxygen Concentrators, Biological Sterilization Indicators,

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 234220929-11
Effective date: 2025-01-08
Expiry date: 2027-10-31
Issue date: 2025-01-08
Replaces certificate SX 2247538-1 issued 2024-10-25

This certificate can be validated on <https://www.certipedia.com>

Melissa DiBuono-Russo
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Chemical/Physical Sterilization Process Indicator, Illuminated Instruments, Suction and Irrigation systems, Cryotherapy Devices, Balloon Dilation Catheter Systems, Absorbable Nasal Implant system, Probing Instruments, Anesthesia Needles, Wireless Camera Systems, Blood Loss Estimation and Surgical Sponge-counting Software Systems, and Procedural Oxygen Masks.

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Stryker Instruments, a division of Stryker Corporation 1941 Stryker Way Portage MI 49002 USA	Activities related to Design and Development, and Administration.
/02	c/o Stryker Instruments, a Division of Stryker Corporation 6201 South Sprinkle Road Portage MI 49002 USA	Activities related to Service
/03	c/o Stryker Instruments, a division of Stryker Corporation 3600 Holly Lane North Plymouth MN 55447 USA	Activities related to Design and Development

This certificate can be validated on <https://www.certipedia.com>